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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,974	08/09/2000	Thomas Teufel	381-86	5643

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/635,974	TEUFEL, THOMAS	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The applicant has timely traversed the non-final rejection in the reply filed on 11/172006, and a response to the arguments is set forth.

2. Claims 1, 3-5 and 46-48 are under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior office action.

Rejections Maintained

4. The rejection of claims 1, 3-5 and 46-48 under 35 USC 112, first paragraph is maintained.

The applicants argue that the examiner has cited specific passages of references that allegedly support his belief, while ignoring other relevant portions of those references that indicate the use of an antibody alone, and points to various instances within the references where the use of anti-EGFR antibodies alone to treat EGFR-related cancers is disclosed (pages 4-6 of the remarks filed on 11/17/2006).

The above arguments are carefully considered but not found persuasive because of the following reasons. The applicants arguments are directed towards the use of EGFR antibodies towards cancer. While the references cited in the previous office action for enablement purposes are directed towards the use of EGFR antibodies for cancer therapy, it is to show that the there are very many variations in the treatment of

EGFR related diseases with an EGFR antibody. Not one standard EGFR antibody is used to treat all the EGFR related diseases.

The applicant is directed to the examples within the specification where it discloses the administration of a combination of the antibody C225 and a chemotherapeutic agent (CPT-11 or cisplatin) to a patient that human cancer, thus it is not clear whether the psoriasis was improved because of the C225 administration, the chemotherapeutic agent (CPT-11 or cisplatin) administration, of the combination of two. Disclosure of treatment of a human with psoriasis, comprising systemically administering to said human an amount of an EGFR/HER1 antibody in combination with a chemotherapeutic agent is insufficient support for claims which are broadly drawn to a method of treating psoriasis using the antibody alone. Hence, the scope of claims is broadly drawn to the treatment of psoriasis with an EGFR antibody and does not commensurate in scope of what the applicant is discussing.

The applicant's response is silent in regard to the lack of guidance and working examples in the art/specification. A mere contemplation of the treatment of the hyperproliferative diseases with an EGFR antibody or other EGFR antagonist, and the data presented in the examples of the instant application does not convince one skilled in the art that the applicant is enabled for the scope of the invention as claimed. Neither did the applicants provide any correlation between cancer and psoriasis, nor did they provide any reference statements within the specification that would lead one of skill in the art to be enabled to practice the full scope of the invention.

On page 6 of the remarks filed on 11/17/2006, the applicant states that "one of skill in the art would conclude that it is likely that the psoriasis resolution described in applicant's disclosure resulted from administration of the anti-EGFR/HER1 antibody, rather than from administration of irinotecan or coadministration of the agents". However, the disclosure only shows that the treatment of psoriasis with anti-EGFR/HER1 antibody and cisplatin; further in example 2, the specification shows the treatment of a human patient with psoriasis and colon cancer with the combination therapy. Thus, in view of the unclear teachings of the specification concerning the identity of the second drug combined with the C225 antibody, the lack of controls demonstrating that the C225 antibody would be effective if used alone for the treatment of psoriasis, the lack of animal models, the practice of the claimed inventions would require further and undue experimentation on the part of the skilled worker.

Further, Varani teaches that there are no good experimental animal models of psoriasis suggesting that the treatment studies for psoriasis are not completely understood for evaluating the therapy of an agent, such as an antibody in this instant. Thus, without teaching or suggesting any mechanism of action, and providing any guidance as to rational design for antagonists of other EGFR ligand stimulated disorders, one of skill in art would not be enabled to practice the full scope of the invention.

5. The rejection of claim 48 under 35 USC 112, first paragraph is maintained.

The applicant has amended claim 48 wherein "C225" is replaced with "chimeric 225". However, as defined in the specification C225 is the chimerized version of the 225 antibody (page 10 lines 17-19, in particular). By simply amending the claim to define the letter "C" does not obviate the deposit rejection. Therefore, the applicant is still required to provide the deposit information for the claimed antibodies and provide all the necessary information to show that the antibodies are publicly available, because chimerized 225 is C225. Further, the applicants response is silent in regard to the deposit information of the 225 antibody.

Hence, the rejection is maintained.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi Ph.D.
(571) 272-8789

SHEELA HUFF
PRIMARY EXAMINER